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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/767,387	01/28/2004	Der-Yang Tien	3054P	4748

7590 02/12/2007

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EXAMINER	
SHAHRESTANI, NASIR	
ART UNIT	PAPER NUMBER
3737	

SHORTENED STATUTORY PERIOD OF RESPONSE	MAIL DATE	DELIVERY MODE
3 MONTHS	02/12/2007	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

If NO period for reply is specified above, the maximum statutory period will apply and will expire 6 MONTHS from the mailing date of this communication.

Office Action Summary	Application No.	Applicant(s)	
	10/767,387	TIEN, DER-YANG	
	Examiner	Art Unit	
	Nasir Shahrestani	3737	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on *28 January 2004*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-32* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☒ Claim(s) *8-11* is/are allowed.

6)☒ Claim(s) *1-7, 12-32* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *01/28/2004* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *1/28/2004*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 1-7, 12-16, are rejected under 35 U.S.C. 103(a) as being unpatentable over Zhong et al. (US 6298264 B1) in view of Vaezy et al. (US 2005/0038340 A1) and in further view of Dev et al. (US 6654636 B1).

Zhong et al. teaches a method for leading macromolecule substances into living target cells (title), comprising: injecting tiny bubbles (shock wave, fig. 2) into tissue. Zhong et al. does not teach 3-D imaging not does it teach wherein the shock wave produces holes on the living tissue. Vaezy teaches ultrasound therapy comprising the steps of picking up 3D structural (CT) and photographic (MRI) images of a tissue or organ (par. [0016], [0069]) and teaches merging or superimposing structural and photographic images (par. [0012]), and choosing or selecting a blood vessel passage fully covering target cells (claim 3) that can be utilized to inject macromolecules. Dev et al. teaches injecting tiny bubbles or electric fields to create pores in cells that are temporary and do not cause permanent damage to cells (col. 2 lines 20-33). It would have been obvious to one of ordinary skill in the art at the time of the invention to have modified the method and apparatus as taught by Zhong et al. to further include the CT and MRI superimposed imaging of structures and blood vessels as taught by Vaezy et al. in order to provide for accurate imaging of the vasculature structure and to improved agent efficacy through

ultrasound therapy (Vaezy et al., title). It would have also been obvious to have further modified the system and method as taught by Zhong et al. in view of Vaezy et al. to further include the use of tiny bubbles as taught by Dev et al. to create non-permanent pores before injecting macromolecules within target tissue so that the tissue can better absorb large molecules without significant damage (col. 2 lines 20-33). Zhong et al. further teaches the microbubbles produced acoustically with initial nuclei being less than 10 microns in diameter (col. 15 lines 47-57) and exerting energy of at least 1 Mpa than can be used to form non-permanent holes (claim 11).

Regarding claims 10 & 13, Zhong et al. does not teach using a pipe to inject substance into target cells. Dev et al. teaches wherein macromolecule substance is injected using a pipe (injection needle 120). It would have been obvious to one of ordinary skill in the art at the time of the invention to have modified Zhong et al. in view of Vaezy et al. to further include the pipe as taught by Dev et al. to inject macromolecule substance into target tissue in order to provide for better absorption by the tissue by providing in vivo contact (Dev et al., fig. 1).

Claim 17-32 are rejected under 35 U.S.C. 103(a) as being unpatentable over Vaezy et al. (US 2005/0038340 A1) in view of Donovan (US 6654636 B1).

Regarding claims 17-25, 27, Vaezy et al. teaches a system for leading macromolecule substances into living target cells (see title), comprising: an image pickup unit used for 3D structure images (MRI) and 3D blood vessel (CT) images (par. [0069]). Vaezy further teaches choosing a blood vessel passage fully covering target cells for transmitting macromolecule substances (claim 3). Vaezy et al. also teaches an injection unit for transmitting macromolecule

substances (par. [0016]) and an energy conversion module (excitation frequency generator 56) used to perform biological effects. Vaezy et al. does not teach a merging unit. Donovan teaches a merging unit for merging CT and MRI images (col. 18 lines 60-67). It would have been obvious to one of ordinary skill in the art at the time of the invention to have modified Vaezy et al. to further include a merging unit as taught by Donovan in order provide for clear target confirmation (Donovan, col. 19 lines 1-3).

Regarding claims 26 & 28, Vaezy et al. further teaches the use of a data processing electronic device (element 210) to lead macromolecules to the target site.

Regarding claims 29-32, Vaezy et al. further teaches a display unit for showing merging data and images and the injection process using a computer-aided apparatus (fig. 22, par. [0067]).

Allowable Subject Matter

Claims 8-11 are allowed. The prior art of record teaches all the limitations of claims 8-11 but does not teach "injecting synthetic blood" in order to produce non-permanent holes within a target tissue site.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Nasir Shahrestani whose telephone number is 571-270-1031. The examiner can normally be reached on Mon.-Thurs: 7:30-5:00, 2nd Friday: 7:30-4:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Brian Casler can be reached on 571-272-4956. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Nasir Shahrestani
1/25/2007

BRIAN L. CASLER
SUPERVISORY PATENT EXAMINER
TECHNOLOGY CENTER